

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

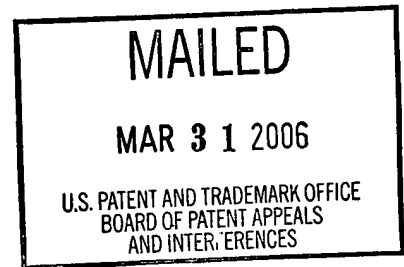
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte DESMOND MASCARENHAS

Appeal No. 2006-0188
Application No. 09/399,120

ON BRIEF



Before ADAMS, MILLS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-10, 16 and 18-50. Claims 1 and 16 are representative of the subject matter on appeal, and read as follows:

1. A method for slowing the growth rate of a tumor, comprising:
administering an effective amount of uncomplexed null insulin-like growth factor I (IGF-I) to a subject having cancer.
16. A method for slowing progression of a cancer comprising: administering an effective amount of uncomplexed null insulin-like growth factor I (IGF-I) to a subject having cancer, thereby slowing progression of the cancer.

Claims 1-10, 16, 18-50 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. After careful review of the record and consideration of the issue before us, we reverse.

DISCUSSION

Claim 1 is drawn to “[a] method for slowing the growth rate of a tumor, comprising: administering an effective amount of uncomplexed null insulin-like growth factor I (IGF-I) to a subject having cancer.” As defined by the specification at page 5, a null IGF-I “refers to IGF-I which has amino acid sequence alterations at one or more sites in the molecule,” and “retains its ability to bind to IGFBP-3, but is altered in its receptor binding and/or activating properties (e.g., having little or no binding to the type I IGF receptor while maintaining its binding activities for the type 2 IGF receptor and the insulin receptor.)”

Claims 1-10, 16 and 18-50 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Examiner’s Answer, page 4.

The examiner bears the initial burden of showing nonenablement. See In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

“[E]nablement requires that the specification teach those in the art to make and use the invention without ‘undue experimentation.’ . . . That some experimentation may be required is not fatal; the issue is whether the amount of

experimentation required is 'undue.'" In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (emphasis in original). Some experimentation, even a considerable amount, is not "undue" if, e.g., it is merely routine, or if the specification provides a reasonable amount of guidance as to the direction in which the experimentation should proceed. See In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The examiner goes through the Wands factors in rejecting the claims, see In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988), concluding "that one skilled in the art could not practice the invention without undue experimentation," Examiner's Answer, page 4.

The examiner's first large concern as to the state of the prior art appears to be that "[t]he state of the art with respect to animal models indicate that xenograft mouse models are poor predictors to tumor behavior in humans." Id. It is unclear, however, what model would be predictive given the statement that "the fundamental problem in cancer research is that model systems are not predictive of in-vivo activity." Id. at 5.

From these statements, it appears that the examiner is of the opinion that a cancer therapy is not enabled until it is clinically available to humans. However, this is not the legal standard to be applied.

As explained in In re Brana, 51 F.3d 1560, 1567, 34 USPQ2d 1436, 1442 (Fed. Cir. 1995), the USPTO should not confuse "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption," citing Scott v. Finney, 34 F.3d

1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir. 1994). The rejection before the court for review in *Brana* was under 35 U.S.C. § 112, first paragraph (enablement). However, the court discussed the issues raised in the appeal in the context of both enablement and the utility requirement of 35 U.S.C. § 101. The court went on to state in *Brana*, 51 F.3d at 1568, 34 USPQ2d at 1442-43:

On the basis of animal studies, and controlled testing in a limited number of humans (referred to as Phase I testing), the Food and Drug Administration may authorize Phase II clinical studies. See 21 U.S.C. § 355(i)(1); 5 C.F.R. § 312.23 (a)(5), (a)(8) (1994). Authorization for a Phase II study means that the drug may be administered to a larger number of humans, but still under strictly supervised conditions. The purpose of a Phase II study is to determine primarily the safety of the drug when administered to a larger human population, as well as its potential efficacy under different dosage regimens. See 21 C.F.R. § 312.21(b). FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. . . . Usefulness in patent law, and in particular the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

In re Brana, 51 F.3d, 1560, 1568 34 USPQ2d 1436, 1442-43 (Fed. Cir. 1995) (citations omitted).

The examiner's second large concern with respect to the state of the art, as well as the predictability or unpredictability of the art is that "the art has recognized the difficulty in determining the three dimensional structure of a

peptide based solely on its structure.” Examiner’s Answer, page 5, see also id. at 6.

This concern appears to be based on the determination of other null-IGF-I proteins, a 70 amino acid long protein, which have amino acid sequence alterations at one or more sites in the molecule, while retaining their ability to bind to IGFBP-3, but altered in their receptor binding and/or activating properties.

The examiner’s last concern appears to be that “[a]lthough the specification provides guidance on how to make the peptides of the claimed invention, the specification has not provided ample guidance [as to] the effectiveness of peptides as inhibiting the growth rate of a tumor.” Examiner’s Answer, page 7. The examiner goes on to state that “[t]he working examples are limited to a single peptide, Y60L IGF-I, which was shown to be effective against prostate cancer,” id., and that “the claims are drawn to the treatment of all cancers,” but “the specification has only shown effectiveness towards a single type of cancer,” id. at 9.

The rejection concludes:

Since, the is [sic] uncertain to predict the helical structure of amino acid sequences based on structure alone, since contemporary hardware falls eight to nine orders of magnitude short of the task, and since different aspects of biological activity cannot be predicted a priori but must be determined from the case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue “painstaking experimentation study” to determine if the peptides would be effective in slowing the growth rate of tumors in a subject having cancer.

Id. at 10.

With respect to the unpredictability of predicting function from sequence, the examiner's discussion is drawn to proteins in general, and is not directed to issues that may arise specifically with null IGF-I. Moreover, as noted by appellants, the specification discusses modifications that may be made to a IGF-I molecule to result in a null IGF-I. See Appeal Brief, page 5. Thus, the specification teaches at page 5 that:

Examples of null IGF-I include variants in which one or more of IGF-I's tyrosine residues (i.e., residues 24, 31, or 60) are replaced with non-aromatic residues (i.e., other than tyrosine, phenylalanine or tryptophan), variants where amino acid residues 49, 50, 51, 53, 55 and 56 are altered (for example, where residues 49-50 are altered to Thr-Ser-Ile or where residues 55-56 are altered to Try-Gln), and combinations thereof.

The examiner has not provided any evidence or reasoning specific to the null IGF-I, other than the assertion that it is unpredictable to go from structure to function, as to why the null IGF-I proteins disclosed in the Specification will not work in the claimed methods. Moreover, as taught by the specification, a null IGF-I has amino acid sequence alterations at one or more sites in the molecule, while retaining its ability to bind to IGFBP-3, but is altered in its receptor binding and/or activating properties, and the examiner has not addressed why it would require an undue amount of experimentation by the skilled artisan to make variants and then test them for the required properties. As noted above, some experimentation, even a considerable amount, is not "undue" if, e.g., it is merely

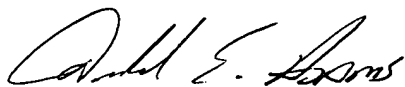
routine, or if the specification provides a reasonable amount of guidance as to the direction in which the experimentation should proceed.

With respect to the examiner's concern that the claims are drawn to the treatment of all cancers, but the specification has only shown effectiveness towards a single type of cancer, again, the examiner has not provided evidence or reasoning specific to the use of null-IGF-1 in the treatment of cancer why it would require an undue amount of experimentation to test the null IGF-1 against different types of cancers using the example provided by the specification, Example 2, page 11, as a guide.

CONCLUSION

Because the examiner has failed to meet the burden of setting forth a prima facie case of lack of enablement, the rejection is reversed.

REVERSED



Donald E. Adams
Administrative Patent Judge



Demetra J. Mills
Administrative Patent Judge



Lora M. Green
Administrative Patent Judge

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